REMARKS

Rejections under 35 U.S.C. § 101

Claims 5-10, 12-14, 39 and 42 are rejected under 35 U.S.C. § 101 for lack of patentable utility. The Examiner contends that the disclosed uses for the invention do not provide a specific or substantial asserted utility or a well established utility.

Applicants have canceled claim 10. Thus, this rejection, as it refers to claim 10, is moot and should be withdrawn. Applicants disagree that this rejection applies to pending claims 5-9, 12-14, 39 and 42.

The Examiner's attention is directed to the Manual of Patent Examination Practice (MPEP), 8th Edition, Rev. 2, May 2004, Chapter 2107, which states that only one credible assertion of specific and substantial utility need be specified for an invention:

Page 2100-29:

> (1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

Page 2100-32:

> ***Specific Utility***
>
> A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful"

invention may arise from what has been disclosed by the applicant. *Knapp v. Anderson*, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).

Substantial Utility

A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

[underline added for emphasis]

Applicants submit that at least one asserted substantial and specific utility exists for the claimed invention and is readily apparent based on the teachings of the specification. For example, in Example 2 beginning on page 214 of the specification, the expression of genes of the invention were assessed quantitatively using RNA samples from a variety of normal and pathology-derived cells, cell lines and tissues by real time quantitative PCR (RTQ PCR). Results for NOV1b, nucleic acid of SEQ ID NO: 3, are found in the specification beginning on page 226. More specifically, results obtained from Panel CNS_Neurodegeneration_V1.0 are shown in Table 18 on pages 226-228 and summarized on page 243. On page 243, the specification teaches:

"Panel CNS_Neurodegeneration_V1.0 shows a moderate increase (1.5 to 2-fold) in the temporal cortex of the Alzheimer's disease brain when compared to non-demented elderly either with or without a high amyloid plaque load ..."

One of skill in the art, having read the specification, would therefore know to detect and compare the amount of expression of the nucleic acid of SEQ ID NO:3, as a marker for Alzheimer's disease.

In addition, results obtained from Panel 1.2 are shown in Table 19 on pages 228-229. In all 6 kidney cancer samples represented on this panel, the nucleic acid of SEQ ID NO: 3 was expressed at a lower level than the level in the normal kidney control or the normal fetal kidney control. One of skill in the art, having read the specification, would therefore know to detect and

compare the amount of expression of the nucleic acid of SEQ ID NO:3, as a marker for kidney cancer.

The distinguishing between diseased and healthy tissue types demonstrates a specific and substantial "real world" use. Applicants assert that the specification identifies that the differential expression of SEQ ID NO: 3 allows for the distinction between tissue types.

Consistent with the teachings of the specification, Applicants respectfully submit that it would be clear to the skilled artisan that the nucleic acid of the present invention is useful, for example, as a marker to distinguish between normal kidney and kidney cancer tissue, and as a marker for Alzheimer's disease, and thus has a credible, specific and substantial utility. Therefore, applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 101.

Rejection under 35 U.S.C. § 102

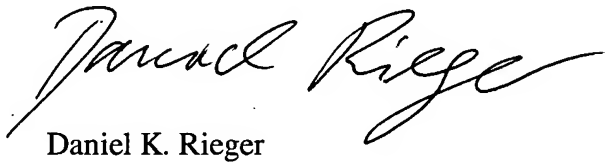
Claims 10 is rejected under 35 U.S.C. § 102(b). Applicants have canceled claim 10. Thus, this rejection is moot and should be withdrawn.

Claims 10 has been canceled. No claims have been amended. Upon entry of this amendment, claims 5-9, 12-14, 39 and 42 will be pending

CONCLUSION

On the basis of the foregoing remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding this response, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted on this 16th Day of March, 2005



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